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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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22428 7590 01/28/2005

FOLEY AND LARDNER
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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT PAPER NUMBER

1614

DATE MAILED: 01/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/600,868

Applicant(s)

LIPSON ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

A Preliminary Amendment filed April 16, 2004 is acknowledged. Claims 1-10 are canceled. New claims 11-26 are presented and represent all of the claims now under consideration. Priority is established.

An Information Disclosure Statement filed June 23, 2003 is further acknowledged. The references have been reviewed to the extent each is a proper citation on a U.S. Patent, a publication date is provided and is available to the Examiner.

A list of co-pending and related applications is requested when Applicants respond to this Office Action.

Claims 10-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the treatment or prevention of mastocytosis, allergy-associated chronic rhinitis, a mast cell tumor and a gastrointestinal stromal tumor. The specification mentions gastric carcinoma cell lines and mast cell disease, such as mastocytosis, but fails to provide support for the claimed methodologies. Inhibition of tyrosine phosphorylation of c-kit in MO7E cells, a human myeloid leukemia cell line, in response to ligand stimulation with stem cell factor is disclosed

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

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- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treatment or prevention of mastocytosis, allergy-associated chronic rhinitis, a mast cell tumor and a gastrointestinal stromal tumor.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the fields of oncology or molecular biology.

Each particular disease that is modulated by mast cell function has its own specific characteristics and etiology. The broad recitation "modulating c-Kit tyrosine protein kinase function" is inclusive of many pathologies that presently have no established successful therapies and are presently unpredictable in their therapeutic outcome.

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It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad and inclusive of diverse pathologies potentially having in common only a relation to mast cell function.

The amount of direction or guidance provided and the presence or absence of working examples

No working examples are clearly associated with the prevention or treatment of mastocytosis, allergy-associated chronic rhinitis, a mast cell tumor or a gastrointestinal stromal tumor.

The quantity of experimentation necessary

Although formulations and routes of administration are disclosed, Applicants have failed to provide guidance as to how a cellular or catalytic assay extrapolates to prevention of a gastrointestinal stromal tumor or mast cell tumor. The skilled artisan would expect the interaction of a particular compound in the treatment of a particular disease state to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for each agent. The instant specification sets forth no such understanding or any criteria for extrapolating beyond the effect of the two claimed compounds to inhibit tyrosine phosphorylation of c-kit in the single cell line, MO7E. No direction is provided to treat or prevent an actual disease. Absent reasonable *a priori* expectations of success for using one of the claimed compounds to

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treat or prevent a gastrointestinal stromal tumor, mastocytosis or mast cell tumor, one skilled in the immunology or oncology art would have to test extensively the various types of tumors and mastocytotic conditions to discover which responds to administration of one of the claimed compounds. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached at 571-272-0591. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

Phyllis G. Spivack

Primary Examiner

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**PHYLLIS SPIVACK
PRIMARY EXAMINER**

January 23, 2005